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January 8, 2002

The Honorable David M. Walker
Comptroller General of the United States
United States General Accounting Office
441 G Street NW
Washington, D.C. 20548

Dear Mr. Comptroller:

I am writing to request that you conduct a study of the manner in which federal agencies administer, use, and benefit from intellectual property created under federally sponsored research programs related to public health, health care and medical technology. As a senior Member of the House Energy and Commerce Committee, which has jurisdiction over biomedical research and development, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and health care (including Medicaid, other federal programs and prescription drugs), and as a Co-Chair of the Task Force on Alzheimer's disease, I am concerned that many important federally funded medical discoveries may not end up fully benefiting taxpayers through their incorporation into inexpensive and widely available medical treatments, equipment and diagnostics, or through their widespread availability to other federally funded researchers.

For example, the Bayh-Dole Act of 1980, several Presidential Executive Orders and subsequent legislation were intended to allow the recipients of federal funding to patent, take title to and profit from inventions funded by the taxpayer. In return, the federally funded inventor had to comply with certain reporting requirements, and the government retained a nonexclusive, nontransferable, irrevocable and royalty-free right to use the inventions. Several recent reports have highlighted problems with the implementation of the law and associated regulations, and have raised questions as to whether the Federal government is either getting its royalty-free license, or using it when it is obtained.

In August 1999, a GAO report entitled "Reporting Requirements for Federally Sponsored Inventions Need Revision" concluded that federal agencies and their contractors and grantees were not complying with Bayh-Dole Act requirements regarding disclosure of federally-funded inventions to the sponsoring federal agency and the U.S. Patent and Trademark Office (PTO.) Moreover, the report stated that GAO's review of more than 2,000 patents, as well as a draft Inspector General report on 12 large grantees of the NIH (the final report never issued), found that "the databases for recording the government's royalty-free licenses are inaccurate, incomplete, and inconsistent and that some inventions are not being recorded at all. As a result, the

government is not always aware of federally sponsored inventions to which it has royalty-free rights."

Press reports have detailed an ongoing Federal investigation of whether the government obtained royalty-free prices on its own scientists' purchases of Applera Applied Biosystem's gene sequencer, the development of which, according to both National Science Foundation (NSF) and California Institute of Technology press releases issued in 1985, used NSF funds. Although these sequencers are used by many federally funded scientists to understand the human genome and the genetic causes for disease and to assist with the development of genetic diagnostics and cures, these scientists have reportedly had to pay full price for them. If the Bayh-Dole Act had been used to ensure that federally funded purchasers of the machines obtained a royalty-free discount, taxpayers would have saved tens of millions of dollars, according to some estimates.

Other reports have detailed one scientist's quest to ensure that software developed using federal funds be publicly available (www.openinformatics.org), which would save other scientists time and money that could be better spent doing other research. It seems to me, however, that under the Bayh-Dole Act, federally funded researchers should already be able to use such software without fear of being sued for patent infringement. In both examples, less expensive or free access to vital medical research tools could certainly speed the way towards less expensive cures for disease and other medical treatments.

As the field of biotechnology continues to grow at an exponential pace, interest in the results of federally funded research into genomics and proteomics, stem cells, advanced biomaterials, and advanced computing (and associated intellectual property) will continue to be shared by both academia and the private sector. As the private sector uses the results of this research to develop new diagnostics and treatments for Alzheimer's disease, cancer, and other illnesses, it will become increasingly important to ensure that the taxpayers who paid for the discoveries can obtain them as easily and as inexpensively as possible.

In order to clarify the extent to which the federal government is benefiting from royalty-free licenses to inventions in the fields of medical/biotechnology, and to better assess the level of compliance by patent holders in this field with existing royalty-free requirements, I ask that the GAO provide me with a report detailing the results of its study into this matter. This report should include answers to the following questions:

1. Who is eligible to use or benefit from the government's royalty-free licenses in medical/biotechnology inventions created under federally sponsored research? Specifically, to what extent are the benefits available to

    a. Federal agencies?
    b. Federal contractors?
    c. Federal grantees?

d. Scientists involved in other federally sponsored research?
e. Participants in federally regulated programs, such as those benefiting veterans, the elderly, and the poor?
f. Others?

2. To what extent have these individuals, organizations, programs, etc., actually used or benefited from the government's royalty-free licenses in inventions created in the medical/biotechnology research areas? Specifically, have the licenses resulted in

   a. Reduced prices in the procurement of items incorporating the inventions?
   b. Contracts for production of the items with contractors other than the patent owners and their licensees?
   c. Use of the inventions for research without having to obtain separate licenses?

Thank you for your attention to this important matter. If you have any questions or concerns, please have your staff contact Dr. Michal Freedhoff in my office at 202-225-2836. I also request that you direct the appropriate GAO staff to contact Dr. Freedhoff to discuss this request, provide my office with periodic briefings on progress made in responding to it, and establish a schedule for submission of a final report.

Sincerely,

Edward J. Markey

Edward J. Markey
Member of Congress